REMARKS/ARGUMENTS

In response to the Office Action mailed September 16, 2009, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, Claim 1 is amended, no claims have been added, or cancelled without prejudice, and claims 9 and 10 have been previously withdrawn so that Claims 1, 4, 5, and 9-10 are currently pending. No new matter has been introduced.

Claims 1, 4 and 5 were rejected as being unpatentable over EP0041795A2 to Sehgal in view of U.S. Patent Publication No. 2004/0167152 to Rubino et al. (Rubino). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

Sehgal discloses an injectable composition of rapamycin. The composition provides for 1 to 20 milligrams of rapamycin per milliliter of the composition and a nonionic surfactant. Various concentrations are illustrated. The injectable rapamycin composition comprises rapamycin, a nonionic surfactant and water. Upon removal of

the solvent, the rapamycin remains in solution in the nonionic surfactant. Dilution of the above solutions containing rapamycin, solvent and nonionic surfactant or rapamycin and nonionic surfactant are made with water.

Rubino discloses parenteral formulations of rapamycin 42-ester with 3-hyroxy-2-(hydroxymethyl)-2-methyl-propionic acid. Essentailly, this patent publication discloses solubilizing CCI-779 with a parenterally acceptable co-solvent accompanied by the presence of an antioxidant and/or chelating agent in the solution. Parenteral generally refers to a means of administration that involves piercing the skin or mucous membrane, typically via injection.

Neither of the references, whether taken alone or in combination disclose or suggest the invention of independent claim 1. Sehgal discloses an injectable composition of rapamycin that comprises no vitamin E in the final product. In addition, it is diluted with water for injection. There is no stable solution containing water. Rubino also fails to disclose a water based solution. It is respectfully submitted that vitamin E TPGS has been known for at least 20 years as a water soluble version of vitamin E and as an excipient for pharmaceutical applications. It is specifically stated on page 4, lines 20 to 25 that it is an injectable aqueous formulation and not a stable one. "Dilution of the above solutions containing rapamycin, solvent nonionic surfactant or rapamycin ... suitable for injection. This dilution is preferably made shortly before administration, e.g. within four hours before injection..." This is an admission that it is not a stable solution as is now very clearly set forth in amended claim 1. It is extremely important to note that the combination of references fail to even remotely suggest the water solution of specific concentrations claimed in independent claim 1. The data for amendment comes from Table 9. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview of the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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